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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/478,387	06/07/95	GRAY	J 028723-061

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EXAMINER

MARSCHEL, A

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

08/478,387

Applicant(s)

Gray et al.

Examiner

Ardin Marschel

Group Art Unit

1634



☒ Responsive to communication(s) filed on Mar 3, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1 and 48-50 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1 and 48-50 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

If an applications wishes to have priority benefit under § 120 to a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

Applicants' arguments, filed 3/3/99, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1 and 48-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Weissman et al., taken in view of Lichter et al. and either of Rowley et al. (P/N 5,487,970) or Drabkin et al.

This rejection is reiterated and maintained as given in the previous office action, mailed 9/3/98. Applicants firstly argue that Weissman et al. lacks specific limitations such as interphase targets and chromosome 3/17 rearrangement. These arguments are non-persuasive because the combination of references supports this rejection. Arguing that a single reference lacks any particular limitation is not directed to the basis for the rejection which is said combination of references and therefore non-persuasive. Applicants then argue that priority should be granted to the instant claims to the two earliest filed parent applications, 06/819,314 and 06/937,793. This argument is non-persuasive because priority is granted only to disclosures that fully support a claim. In the instant claims the 3/17 rearrangement is not supported in these parent

applications. Applicants argue that such support is implicit in the invention being specific to single chromosomes. This is non-persuasive for two reasons. Firstly, a rearrangement between chromosomes 3 and 17 is specific to two and not a single chromosome. Secondly, implicit support is not written support. Support must be explicit in order to support a granting of priority. In summary, the arguments of applicants against this rejection are non-persuasive. The basis for the rejection is repeated hereinunder below for completeness of this Final action.

Weissman et al. as summarized of record discloses the preparation of large unique sequence probes sets for hybridization assay of various chromosomal abberations including translocations. Motivation for assaying translocations is given in column 2, lines 13-39. The study of gene organization, of which translocations are clearly one type, are the subject of the Weissman et al. invention as noted in column 5, lines 53-58. Weissman et al., however, does not disclose interphase target assays nor specifically assaying directed to translocations in chromosomes 3 and/or 17.

Lichter et al. discloses interphase target assays for genetic abnormalities utilized in an hybridization assay format. Several chromosomal regions which are distinctly detectable in such interphase samples are described in the paragraph bridging the first and second columns on page 9664. This discription and

the results in Lichter et al. give a reasonable expectation of success for such interphase assays.

Rowley et al. disclose in column 2, lines 9-22, chromosome 17 translocations as motivated targets regarding acute leukemia. The paracentromeric location of these translocations is suggested in column 2, lines 35-38. This is motivation to assay for such translocation events.

Drabkin et al. in the abstract discloses a translocation involving chromosome 3 as being reported in a family with renal cell carcinoma. Other familial chromosome 3 translocations in the paracentromeric region is described in the paragraph bridging the first and second columns on page 6980. This is motivation to such such translocation events.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the instant invention because Weissman et al. generically suggests and motivates chromosomal abnormality hybridization assays with large unique probe sets. Lichter et al. describes hybridization assays utilizing interphase targets. Hybridization assays are generically utilized by Weissman et al. for the invention therein disclosed. Rowley et al. and Drabkin et al. describe and motivate chromosomes 17 and 3, respectively, as targets for hybridization assay due to translocations involving these chromosomes. These disclosures together motivate and thus

describe the instant invention.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 48-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 72, 75, 78, 81, 84, 88, 89, 96, and 97 of copending application Serial No. 08/487,701; and claims 1 and 48-50 of 08/477,316; although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending applications contain common embodiments directed to high complexity probe methodology.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Since the fee set forth in 37 CFR 1.17(r) for a first submission subsequent to a final rejection has been previously paid, applicant, under 37 CFR 1.129(a), is entitled to have a second submission entered and considered on the merits if, prior to abandonment, the second submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a second submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-



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4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

May 24, 1999

*Ardin H. Marschel*  
**ARDIN H. MARSCHEL**  
**PRIMARY EXAMINER**